

Improving Evidence Development

The Centers for Medicare & Medicaid Services (CMS) is holding a special Open Door Forum on February 14, 2005 to solicit comments to assist in the development of a draft guidance document concerning Medicare coverage decisions associated with data collection requirements.

CMS is interested in supporting the development of better scientific evidence to ensure improved patient outcomes and efficient health care delivery. We are interested in bridging the “gaps in knowledge”, which is essential to increasing the evidence base that allows physicians and patients to select appropriate diagnostic and therapeutic services. An infrastructure to systematically identify these gaps in knowledge, and conduct appropriate studies to address those gaps is important to the health care of the Medicare beneficiaries.

In developing guidance concerning Medicare coverage decisions associated with data collection requirements, CMS is soliciting comments from the public. In addition to providing comments during our open door forum, interested parties can also submit comments to CAGinquiries@cms.hhs.gov. Some of the questions we wish to explore are:

1. What factors should be considered in selecting technologies for which CMS would link coverage to additional data requirements?
2. Which study designs and methods should be considered to obtain additional evidence?
 - Registries?
 - Observational trials?
 - Randomized Controlled Trials (RCT)?
 - Other methods for prospective evaluation?
3. Who should be involved in the planning and conduct of:
 - Priority Setting
 - Study design
 - Implementation
 - Funding
4. How do we ensure data accuracy?
5. Who should have access to the data collected?
6. How long should the data collection continue?
7. What types of infrastructures will be needed to effectively implement clinical registries?